**PATENT APPLICATION**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re the Application of

Robert P. Hammer *et al.*

Serial No. 10/666,095

Filing Date: September 18, 2003

For: Anti-Fibril Peptides (File 0212.1 Hammer)

Group 1654

Examiner Russel, Jeffrey E.

## AFFIDAVIT OF ROBERT P. HAMMER

**STATE OF LOUISIANA**

**PARISH OF EAST BATON ROUGE**

Robert P. Hammer, being duly sworn, deposes and says:

**1.**

I am a Professor in the Department of Chemistry at Louisiana State University in Baton Rouge, Louisiana. I am one of the co-inventors of the above-captioned patent application. I make this Affidavit in support of this application.

**2.**

Yanwen Fu, Jed P. Aucoin, Tod J. Miller, Mark L. McLaughlin, Robin L. McCarley, and I are the inventors, and are the only inventors, of the subject matter that has been

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**CERTIFICATE**

I hereby certify that this Affidavit of Robert P. Hammer is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on December 20, 2005.

John H. Runnels
Registration No. 33,451
December 20, 2005

claimed in this patent application. Not all co-inventors contributed to the conception of all aspects of all of the claimed inventions, however.

**3.**

The criteria that I understand govern inventorship under United States patent law differ from the criteria commonly used to name authors on scholarly publications such as peer-reviewed papers, PhD dissertations, and presentations made at a meeting of a scientific society. Thus there should be no surprise that the named authors on such works may differ from the named inventors in a related patent application.

**4.**

I understand that among the references that have been cited against the present application are **(a)** Y. Fu *et al.*, "Efficient Acylation of the *N*-terminus of highly hindered $C^{\alpha,\alpha}$-disubstituted amino acid symmetrical anhydrides," *Organic Letters*, vol. 4, pp. 237-240 (2002) (the "*Organic Letters* paper"); **(b)** Y. Fu, *Artificial Peptides Containing $C^{\alpha,\alpha}$-Disubstituted Amino Acids: Synthesis, Conformational Studies, and Application as β-Strand Mimics,* PhD Dissertation (Louisiana State University, Baton Rouge, 2002) (the "Dissertation"); and **(c)** J. Aucoin, "Dissection of an Amyloid Aggregation Inhibitor," presentation at 225th American Chemical Society conference (March 23-27, 2003) (the "Aucoin Presentation").

**5.**

The bottom of the first page of the *Organic Letters* paper states "Published on Web 12/22/2001." I have no reason to doubt the accuracy of this statement. I have no reason to believe that this paper had been published prior to December 22, 2001. I note that this date was less than one year prior to the September 19, 2002 filing date of provisional priority application 60/412,081. It is my understanding that this paper was cited by the Office due to its disclosure of the peptide AMY-1 (SEQ. ID NO. 4) on page 239, col. 1. Dr. McLaughlin and I jointly conceived the structure of the AMY-1 peptide. Dr. Miller conceived the synthesis of the unnatural amino acid dibenzylglycine, one of the components of the AMY-1 peptide. Dr. Fu and I jointly conceived the synthesis of the AMY-1 peptide from its component amino acids, including the non-standard amino acids. Therefore, it is my opinion that the inventors of the peptide AMY-1 are Mark McLaughlin, Yanwen Fu, Tod J. Miller, and me, since each of us contributed to the conception of the structure or of the

synthesis of this peptide. Because the emphasis of the *Organic Letters* paper was on the synthesis of the peptide AMY-1 from its amino acid components, only Dr. Fu and I were named as co-authors of that paper. Because Dr. McLaughlin and Dr. Miller did not directly contribute to the peptide coupling protocols that are the focus of the *Organic Letters* paper, they were not named as co-authors on that paper. Nevertheless, in my opinion Dr. McLaughlin and Dr. Miller are co-inventors of the AMY-1 peptide for the reasons given above. Dr. Aucoin and Dr. McCarley contributed to the conception of other aspects of the claimed inventions, but not the AMY-1 peptide.

**6.**

The title page of the Dissertation shows that it was submitted in December 2002. In the ordinary course of such matters, the Dissertation would normally have become publicly available some weeks or months later, although I have not confirmed the exact date when it became publicly available. I was the author's graduate research adviser (see page ii of the Dissertation, first paragraph). As the author's graduate research adviser, I can state with confidence that the Dissertation was not publicly available before December 2002. I note that December 2002 was less than one year prior to the September 18, 2003 filing date of present application. It is my understanding that the Dissertation was cited by the Office for its disclosure concerning various points. It is in the very nature of a PhD Dissertation that a Dissertation will have but a single author. The presentation of original research in a Dissertation constitutes an implied representation that the author made a significant contribution to the research reported. However, in the absence of some express statement to the contrary, the implied representation does not go so far as an assertion that no one else made any contribution to the reported research. Indeed, most modern scientific research is a collaborative effort, and few would assume that the author of a Dissertation received no assistance in conducting the work described. To the contrary, page ii of the Dissertation, "Acknowledgments," acknowledges the collaboration and assistance of many individuals, including both people who are named as co-inventors on the present application and those who are not. Note particularly that each of the co-inventors of the present application is acknowledged on page ii. It would not be customary to name them (or anyone else) as co-authors on a PhD Dissertation, however. Dr. Fu and I jointly conceived the synthesis of several peptides from their component amino acids,

including non-standard amino acids. To the extent that the Dissertation describes such syntheses, the conception of those syntheses was joint by Dr. Fu and me. Dr. Fu also did most of the hands-on laboratory work in carrying out those syntheses. To the extent that the Dissertation describes other aspects of the claimed inventions, Dr. Fu learned of those aspects of the claimed inventions from me or from our other co-inventors, and to that extent the Dissertation therefore represents a publication (direct or indirect) of the inventors' own work.

**7.**

Although the Aucoin Presentation does not show on its face when it was presented, on information and belief these are copies of slides presented by Dr. Jed Aucoin at the 225th American Chemical Society conference, held March 23-27, 2003. I have no reason to believe that the slides were publicly displayed or otherwise publicly available prior to March 23, 2003. So far as I am aware, these slides were presented only during Dr. Aucoin's presentation, and printed copies were not distributed at the meeting. I note that the March 2003 presentation was less than one year prior to the September 18, 2003 filing date of present application. Abstracts for the presentations at meetings of the American Chemical Society are typically distributed to attendees about one or two months before the meeting. Although I do not have the precise date for distribution of these abstracts, it would certainly have been less than one year prior to the September 18, 2003 filing date of the present application. It is my understanding that a copy of the abstract for this presentation is being cited on an Information Disclosure Citation to be submitted contemporaneously with this Affidavit. It is my understanding that this presentation was cited by the Office due to its disclosure of the peptides AMY-1, AMY-2, and AMY-3 (SEQ ID NOS. 4-6, respectively). The sequences of AMY-1, AMY-2, and AMY-3 were conceived by Dr. McLaughlin and me. Their synthesis was conceived by Dr. Fu and me. The synthesis of the unnatural amino acid dibenzylglycine, one of the components of the AMY-1, AMY-2, and AMY-3 peptides, was conceived by Dr. Miller. To the extent that the presentation discloses these peptides and their synthesis, Dr. Aucoin learned that information directly or indirectly from these other inventors. Dr. Aucoin made the surprising discovery that AMY-2, for example, causes aggregation into a non-toxic, non-fibril conformation, as opposed to inhibiting all aggregation. See for example the conclusions

page of the Aucoin presentation. It is customary that presentations such as this one name a single individual as the author, the person who is to actually give the talk. There is no implication that others did not also contribute to the work as well. Note for example the "acknowledgments" page of the presentation, naming a number of individuals, some of whom are inventors on the present application, and some of whom are not. I note also that the authors on the abstract for this presentation were instead listed as "J.P. Aucoin, M.A. Etienne, R. P. Hammer, M.I. McLaughlin, P.S. Russo, and R. L. McCarley." To the extent that the presentation discloses the peptides AMY-1, AMY-2, and AMY-3 or their synthesis, the non-inventor authors, Dr. Etienne and Dr. Russo, learned that information directly or indirectly from the named inventors. Dr. Russo was named as an author in recognition of his work in light-scattering measurements of the amyloid particles, which was discussed in the presentation but which is not part of the scope of the claimed inventions. Dr. Etienne was named as an author in recognition of his work in re-synthesizing the AMY-1 peptide (SEQ ID NO: 4) according to the methods that had previously been developed by Dr. Fu and Dr. Miller, without substantial modification.

**8.**

All statements made in this Affidavit of my own knowledge are true. All statements made in this Affidavit on information and belief are believed to be true. These statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-identified patent application or any patent issuing from that application.

**Robert P. Hammer**

**SWORN TO AND SUBSCRIBED** before me this 19th day of December, 2005.

**NOTARY PUBLIC**
John H. Runnels
La. Bar Roll No. 17126

My Commission Expires at Death